DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Detroit District
300 River Place
Suite 5900
Detroit, MI 48207
Telephone: 313-393-8100
FAX: 313-393-8139

95082d

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
2005-DT-02

November 23, 2004

Mr. Daniel W. Thuemmel, President
Thuemmel Dairy, Inc.
8774 Thuemmel Road
Port Austin, Michigan 48467

Dear Mr. Thuemmel,

An inspection of your dairy operation located at 8774 Thuemmel Road, Port Austin, Michigan, 48467, conducted by a Food and Drug Administration (FDA) investigator on June 29, 2004, confirmed that you offered at least two animals for sale for human food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act). You also caused the new animal drug gentamicin sulfate to become adulterated within the meaning of Section 501(a)(5) of the Act, because the drug was used in a manner that does not conform with the extralabel use regulations in Title 21 Code of Federal Regulations (21 CFR) Part 530.

On May 12, 2004, you sold an adult dairy cow identified with back tag #[redacted] and neck chain #[redacted] to [redacted] and the animal was in turn sold to [redacted] for slaughter as human food. This cow was slaughtered on this same day and United States Department of Agriculture (USDA) analysis of tissue samples collected from that same animal identified the presence of [redacted] of gentamicin in the kidney and [redacted] gentamicin in the liver.

In addition, on June 1, 2004, you sold an adult dairy cow identified with back tag #[redacted] and neck chain #[redacted] to [redacted] where it was in turn sold to [redacted] for slaughter as human food. This cow was slaughtered on June 2, 2004, and USDA analysis of tissue samples collected from that same animal identified the presence of [redacted] of gentamicin in the kidney.

There is no approved tolerance level for gentamicin in dairy cattle. The presence of this drug in edible tissue from these animals causes the food to be adulterated.

Our investigation also found that you hold animals under conditions which are inadequate in that medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you failed to maintain adequate medication/treatment records to identify

the animal, date of medication, the drug dosage administered, and the drug pre-slaughter withdrawal time. Two examples of this are that there were no drug treatment records for the two dairy cows involved in the violative gentamicin tissue residues, identified with back tags #[redacted] and #[redacted], which were offered for sale and subsequently slaughtered for human food use. Food from animals held under such conditions are adulterated under Section 402(a)(4) of the Act.

You also adulterated the drug gentamicin sulfate within the meaning of Section 501(a)(5) of the Act when you used this drug in dairy cattle, a species for which it is not approved. The extralabel use of an approved animal drug is allowed if the use complies with Sections 512(a)(4) and 512(a)(5) of the Act and 21 CFR Part 530. However, your use of the drug was not in compliance with the extralabel use regulations because you administered it without the benefit of a valid veterinarian client-patient relationship, 21 CFR 530.10(a), and your use of gentamicin resulted in the presence of drug residue in edible tissue that might present a risk to public health, 21 CFR 530.11(c).

The above is not intended to be an all-inclusive list of violations. As a producer of dairy cows that are offered for use as food, you are responsible for assuring that your overall operation and the food you distribute are in compliance with the law. You should take prompt action to correct these violations and to establish procedures to prevent their recurrence. Failure to promptly correct these violations may result in regulatory sanctions without further notice. These sanctions include, but are not limited to, seizure and/or injunction. This letter notifies you of our findings and provides you an opportunity to correct the above deficiencies.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Federal Food, Drug and Cosmetic Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale in interstate commerce by a slaughter facility is sufficient to hold you responsible for violation of the Act.

You should notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Your response should be directed to Ms. Judith A. Jankowski, Compliance Officer, at the above address.

Sincerely yours,

Joann M. Givens
District Director
Detroit District Office